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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KODA & ANDROLIA
2029 CENTURY PARK EAST
SUITE 1140
LOS ANGELES, CA 90067

EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,202	SAKAMOTO, NORIYASU	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Status of Claims

Claims 1-6 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy in combination with two or more of the following: using warm water that is colored in blue, light blue or other colored light; shining said colored light onto the eyes of a patient; allowing said patient to listen to sound such as music; simulating a shiatsu message or acupuncture; and cooling the head of said patient, does not reasonably provide sufficient enablement to one of ordinary skill in the art on how to accurately and reasonably measure, treat and alleviate various conditions of a patient, such as a lack of spiritual concentration, strength and stability, for example, by subjecting said patient to various metals and jewels, as broadly claimed, without an undue amount of experimentation.

An analysis of whether the scope of a particular claim is actually supported by the disclosure in a patent application requires a determination of whether the disclosure, at the time of filing, contained sufficient information regarding the subject matter of the claim at issue so as to enable one skilled in

the pertinent art to make and use the claimed invention without undue experimentation. *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). Therefore, the test of enablement is not whether experimentation is necessary, but rather, if experimentation is in fact necessary, whether it is reasonably considered to be undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).

Determining the issue of enablement with respect to a claim is a question of law based on underlying factual findings. *In re Vaeck*, 20 USPQ 2d 1438, 1444 (Fed. Cir. 1991). More particularly, there are many factors to be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and whether any necessary experimentation is reasonably considered to be "undue." See *In re Wands* at page 1404. MPEP § 2164.01(a). The Court in *In re Wands* set forth the following factors to be considered, which include, without limitation, the: 1. scope or breadth of the claims; 2. nature of the invention; 3. relative level of skill possessed by one of ordinary skill in the art; 4. state of, or the amount of knowledge in, the prior art; 5. level or degree of predictability, or a lack thereof, in the art; 6. amount of guidance or direction provided by the inventor; 7. presence or absence of working examples; and 8. quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure.

The specification merely discloses in Tables 6 and 7, without more, that various conditions of a patient, such as a lack of spiritual concentration, strength and stability, for example, may be treated by subjecting said patient to various metals and jewels. However, Applicant is purporting to alleviate the pathological manifestation and clinical presentation of mental or emotional stress in a patient suffering therefrom or susceptible thereto via utilization of hyperthermia and hydrotherapy. As a result, the claims are broader in scope than the enabling disclosure.

The nature of the invention appears to be directed a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy.

The relative level of skill possessed by one of ordinary skill in the art of treating diseases, disorders and conditions in a patient is relatively high, as a majority of health care workers, such as physicians and nurses, as of the effective filing date of the instant application, possess an M.D. and/or Ph.D., and are registered nurses, respectively.

An extraordinary degree of unpredictability, not to mention a great deal of uncertainty due to a distinct lack of knowledge of the skilled artisan, existed in the state of the prior art regarding how to accurately and reasonably measure, treat and alleviate various conditions of a patient, such as a lack of spiritual concentration, strength and stability, by subjecting said patient to various metals and jewels.

Since a great deal of uncertainty due to a distinct lack of knowledge of the skilled artisan existed in the state of the art at the time the instant application was filed, and because there was an extremely low level or degree of predictability in the art as of the effective filing date of the instant application, the Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy, the specification utterly fails to provide not only working embodiments, but also scientific and statistical data with respect to a method of measuring, treating and alleviating various conditions of a patient, such as a lack of spiritual concentration, strength and stability, for example, by subjecting said patient to various metals and jewels.

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately measure and thereby determine whether the method of the instant application does in fact treat or alleviate a lack of spiritual concentration, strength and stability in a patient by subjecting said patient to various metals and jewels.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of not only working embodiments, but also scientific and statistical data regarding the measurement, treatment and alleviation of a lack of spiritual concentration, strength and stability in a patient utilizing said method, that one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said method would actually treat or alleviate a lack of spiritual concentration, strength and stability in a patient.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, claims 1, 2 and 5 recite various limitations including: "the internal body temperature," "the internal head temperature," and "the bed." However, there is insufficient antecedent basis for these limitations in the claims. In addition, claims 3 and 4, which are dependent upon rejected independent claim 1, are therefore also indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention, and thus likewise rejected as being indefinite under 35 U.S.C. § 112, second paragraph. Furthermore, claim 6, which is dependent upon rejected claim 4, is therefore also indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, and thus likewise rejected as being indefinite under 35 U.S.C. § 112, second paragraph. Appropriate correction is required. In addition, claims 1-4 appear to be directed to a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy, while claims 5-6 appear to be directed to a hydrotherapy apparatus for inducing hyperthermia. However, claim 6 recites an "apparatus of claim 4." If claims 1-4 are in fact drawn to a hydrotherapy apparatus for inducing hyperthermia, said claims should explicitly recite "a hydrotherapy apparatus for inducing hyperthermia, wherein said apparatus comprises ... ." On the other hand, if claims 1-4 are in fact drawn to a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy, then not only should said claims explicitly recite "a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy, wherein said method comprises ... ," but also claim 6 should be dependent upon independent claim 5, which is also directed to a hydrotherapy apparatus for inducing hyperthermia. Appropriate correction is required.

2. Claim 4 is also rejected under 35 U.S.C. § 112, second paragraph, because the recitation of "trace elements are ***copied*** to potassium iodide water," as set forth in claim 4, is confusing (emphasis added). Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,930,851 (hereinafter the Brunelle '851 patent) in view of U.S. Patent 3,902,488 (hereinafter the Sheppard '488 patent).

With respect to claim 1 of the instant application, the Brunelle '851 patent teaches a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy (column 1, lines 6-14; column 3, lines 63-66; column 4, lines 28-31; column 7, lines 47-50 and 58-63; and column 8, lines 49-51). The Brunelle '851 patent does not explicitly teach measuring an internal body temperature of said patient. However, the Sheppard '488 patent teaches a hydrotherapy apparatus for inducing hyperthermia, wherein an intracranial temperature of said patient is measured (column 3, lines 36-47). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method of the Brunelle '851 patent, which induces hyperthermia, so as to measure the internal body temperature and especially the intracranial temperature of a patient. One of ordinary skill in the art at the time the instant application was filed would have been motivated to measure the internal body temperature and especially the

intracranial temperature of a patient so as to avoid hyperpyrexia, as reasonably suggested by the Sheppard '488 patent.

With respect to claim 2 of the instant application, the Brunelle '851 patent teaches a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy, wherein said method comprises: warm water irradiated with colored light (column 2, lines 4-8; column 6, lines 51-60; and column 7, lines 32-35); irradiating eyes of said patient with said colored light (column 2, lines 4-8; column 6, lines 51-60; and column 7, lines 32-35); simulating a therapeutic message treatment similar to that received by a professional message therapist (column 2, lines 1-3; column 3, lines 63-67; column 4, lines 1-8, 12-14 and 28-31; column 7, lines 47-50 and 58-63; and column 8, lines 49-51); and exposing said patient to an electromagnetic field (column 6, lines 66-67; and column 7, line 1).

With respect to claim 3 of the instant application, the Brunelle '851 patent teaches a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy, wherein said method comprises exposing said patient to a hydrothermal aqueous water bath, mineral-rich mud bath or marine mud bath (column 3, lines 63-67; column 4, lines 11-13).

With respect to claim 4 of the instant application, the Brunelle '851 patent teaches a method of treating or alleviating mental or emotional stress in a patient via utilization of hyperthermia and hydrotherapy, wherein said method comprises exposing said patient to a hydrothermal aqueous water bath, mineral-rich mud bath or marine mud bath comprising vital minerals, trace elements, nutrients and other vital and/or active substances, which are parenterally absorbed through skin of a patient via osmosis (column 3, lines 63-67; column 4, lines 1-4 and 11-13; and column 8, lines 19-22). The Brunelle '851 patent does not explicitly teach that said patient ***enterally swallows*** *a rehydration*

beverage comprising trace elements, such as potassium iodide. However, the Brunelle '851 patent does teach a patient ***parenterally absorbing*** trace elements from an aqueous water bath via osmosis through the patient's skin. First, it would have been prima facie obvious to one of ordinary skill in the art that the phrase "trace elements," as taught in the Brunelle '851 patent, includes potassium iodide, which is a trace element. Second, the term "osmosis," as defined by Merriam Webster's Collegiate Dictionary, 10th Edition, means "a process of absorption." Likewise, the term "drink," as defined by Merriam Webster's Collegiate Dictionary, 10th Edition, means to "absorb." Therefore, the teachings of the Brunelle '851 patent renders obvious the claim limitations as set forth in claim 4 since said claim explicitly recites that a patient ***drinks*** *an aqueous trace element* ***solution***, as opposed to a patient ***enterally swallows*** *a rehydration* ***beverage*** comprising trace elements.

With respect to claim 5 of the instant application, the Brunelle '851 patent teaches a hydrotherapy tub for inducing hyperthermia (column 1, lines 6-14; column 3, lines 63-66; column 4, lines 28-31; column 7, lines 47-50 and 58-63; and column 8, lines 49-51). The Brunelle '851 patent does not explicitly teach that said hyperthermia hydrotherapy tub comprises as means for measuring the internal body temperature of said patient. However, the Sheppard '488 patent teaches a hydrotherapy apparatus for inducing hyperthermia, wherein an intracranial temperature of said patient is measured (column 3, lines 36-47). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the hyperthermia hydrotherapy tub of the Brunelle '851 patent so as to measure the internal body temperature and especially the intracranial temperature of a patient. One of ordinary skill in the art at the time the instant application was filed would have been motivated to measure the internal body temperature and especially the intracranial

temperature of a patient so as to avoid hyperpyrexia, as reasonably suggested by the Sheppard '488 patent.

With respect to claim 6 of the instant application, the Brunelle '851 patent teaches a hyperthermia hydrotherapy tub, wherein said hyperthermia hydrotherapy tub comprises: a means for irradiating eyes of a patient with colored light (column 2, lines 4-8; column 6, lines 51-60; and column 7, lines 32-35); a means for simulating a therapeutic message treatment similar to that received by a professional message therapist (column 2, lines 1-3; column 3, lines 63-67; column 4, lines 1-8, 12-14 and 28-31; column 7, lines 47-50 and 58-63; and column 8, lines 49-51); and a means for exposing said patient to an electromagnetic field (column 6, lines 66-67; and column 7, line 1).

2. Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the Brunelle '851 patent in view of the Sheppard '488 patent and in further view of U.S. Design Patent 262,760 (hereinafter the Adams '760 patent) and U.S. Pre-Grant Patent Application Publication 2002/0147152 (hereinafter the Bell '152 publication).

The teachings of the Brunelle '851 patent and the Sheppard '488 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claim 4 of the instant application, the Brunelle '851 patent does not explicitly teach that said patient ***enterally swallows*** *a rehydration* ***beverage*** comprising trace elements, such as potassium iodide, while undergoing hyperthermia and hydrotherapy treatment in a hyperthermia hydrotherapy tub. However, the Adams '760 patent teaches a beverage container holder attachment for a hot tub (Figures 1-6). In addition, the Bell '152 publication teaches a nutritional beverage for not only improving mood, but also relieving chronic stress and symptoms associated therewith, such as

sweating, wherein said nutritional beverage comprises potassium iodide ([0001]-[0002], [0004] and [0040]). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the hyperthermia hydrotherapy tub of the Brunelle '851 patent with said beverage container holder attachment for a hot tub, as taught by the Adams '760 patent. Furthermore, one of ordinary skill in the art would have been motivated to provide a chronically stressed and profusely sweating patient (who is undergoing hyperthermia and hydrotherapy treatment) with a rehydrating nutritional beverage comprising potassium iodide so as to improve the mood and relieve the chronic stress of said patient, as reasonably suggested by the Bell '152 publication.

Conclusion

Claims 1-6 are rejected since the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the claimed invention, as a whole, would have been reasonably suggested by the teachings of the cited prior art references.

Relevant Prior Art

The following is a list of prior art patents and non-patent literature references made of record and considered to be pertinent to the Applicants' disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

U.S. Patent Number 3,623,455, which issued to Kelly et al. on November 30, 1971 (claim 1, which discloses an artificial sea water solution comprising a trace element solution of potassium iodide);
U.S. Patent Number 6,317,903, which issued on November 20, 2001;
U.S. Patent Number 6,669,661, which issued to Yee on December 30, 2003; and

DeFord, J.A., et al., Design and Evaluation of Closed-Loop Feedback Control of Minimum Temperatures in Human Intracranial Tumors Treated with Interstitial Hyperthermia,

Medical and Biological Engineering and Computing, Vol. 29, No. 2, pp. 197-206 (March 1991).

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER